K071899

OCT 2 2 2007

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Traditional 510(k): Device Modification – Envoy Patient Monitor

Terminology

Envoy = Subject of this 510(k). The Envoy Patient Monitor is a modified device, a system identical to of the Envoy Patient Monitor with the addition of BISx module.

SPACELAB MEDICAL BISPECTRAL INDEX (BISX) ANALYSIS – The predicate device. The SpaceLab monitor was cleared for marketing by the FDA (K060900)

Intended Use of the Envoy Patient Monitor

The ENVOY Monitor is a physiological patient monitor intended to be used for monitoring vital signs of critically ill adult and pediatric patients in the hospital environment, such as: ECG/Heart Rate, Invasive Blood Pressure, Respiration, Temperature, Noninvasive Blood Pressure, CO, Pulse Oximetry and $EtCO_2$. The ENVOY may be used to monitor a wide range of patient conditions in many different clinical specialties within the hospital. The device is intended for use by qualified health care providers, who will determine when use of the device is indicated, based upon their professional assessment of the patient's medical condition.

Indications for use - BIS Module

The Mennen Medical Envoy BIS module is intended for use under the direct supervision of a licensed healthcare practitioner or by personnel trained in its proper use. It is intended for use on adult and pediatric patients within a hospital or medical facility providing patient care to monitor the state of the brain by data acquisition of EEG signals.
The BIS Index, a processed parameter may be used as an aid in monitoring the effects of certain anesthetic agents. Use of BIS monitoring to help guide anesthetic administration may be associated with the reduction of the incidence of awareness with recall in adults during general anesthesia and sedation.

- The Bispectral Index is a complex technology, intended for use only as an adjunct to clinical judgment and training.

- ❖ In addition, the clinical utility, risk/benefit, and application of this device have not undergone full evaluation in the pediatric population.

*The Intended Use of the Envoy monitor as indicated above are same as the Indications For Use.

Device Description – Envoy Patient Monitor with BIS module

The Envoy is a multiparameter physiological patient monitor, capable of monitoring:

- ECG/Heart Rate
- Invasive blood pressure
- Non-invasive blood pressure
- Respiration
- Pulse oximetry
- Two temperature channels
- Cardiac output
- EtCo2
- Spirometry
- EEG
- BIS module (new – subject of this application)

The Envoy bedside patient monitor consists of a main processing unit, a mountable color monitor, and a module rack housing the various Mennen Medical plug-in vital signs modules. The modules monitor the patient's vital signs. Up to six internal modules can be plugged into a module rack. The Envoy can accommodate two module racks. The vital sign data derived from the modules by the Envoy are presented on the monitor as waveform and numeric displays. The Envoy vital signs modules acquire vital signs data from the patient, and display their waveforms and alarms indications on the Envoy display unit. Vital signs and waveform information are displayed simultaneously on the Envoy Display Unit. Up to 8 traces can be displayed at any one time.

The vital signs modules interface with readily available physiologic transducers through electrically isolated patient input connections. After amplification, the signals are digitized, analyzed and displayed. All processing and alarm determination for ECG, Respiration and Invasive Blood Pressure is made using proprietary algorithms and software based on previously marketed Mennen Medical monitoring devices tested against well known and accepted data bases that present representative examples of waveform artifact to be encountered in real case conditions. The SpO2, Non-Invasive Blood Pressure, EtCO2 and Spirometry modules incorporate software and/or hardware technology developed by vendors whose products are marketed in the USA.

Information from each vital sign is presented in a separate portion of the display. Each vital sign is labeled for identification and numeric value. Displayed Vital sign information can include: Primary Vital Sign Name, waveform, Vital Sign Numeric Value, Alarm Status Message.

Operation of the Envoy is accomplished by interaction with front panel controls on the main processor unit. A quick-knob control allows direct interaction with displayed menus for direct parameter selection and setup. Where manual entry of alphanumeric information is required, a ' menu keyboard menu is displayed.

The Envoy is a reusable, software driven, patient monitor, intended for use as part of a physiological monitoring system in a hospital environment. As such it is not a life supporting, nor life sustaining device; nor is it implantable and therefore sterility is not a consideration.

The Envoy complies with (amongst others) the following voluntary standards:

- IEC 60601-1: Medical Electrical Equipment – General Requirements for Safety
- IEC 60601-1-2: General Requirements for Safety. Collateral standard: Electromagnetic compatibility – Requirements and tests.
- IEC 60601-2-27: Medical Electrical Equipment – Part 2: Particular Requirements for the Safety of Electrocardiographic Monitoring Equipment.
- IEC 60601-2-30: Requirements for Automatic Cycling Indirect Blood Pressure monitoring.
- AAMI/ANSI SP-10/A1: Electronic or Automated Sphygmomanometers
- IEC 60601-2-34: Requirements for Invasive Blood Pressure monitoring.
- AAMI/ANSI ES1: Safe Current Limits for Electromedical Apparatus, and
- AAMI/ANSI EC13: Cardiac Monitors, Heart Rate Meters and Alarms.

The Envoy is not a kit and does not contain any drug or biological products. The **BIS** module of the Envoy patient monitor is not sold as a stand alone device, but as part of a multiparameter physiological patient monitoring system (Envoy).

In chapter 1 of the Envoy Operating Manual, the following Prescription Notice appears: "Federal United States law restricts the sale and use of this instrument to qualified medical personnel only"

Functional description of the new Envoy BIS Module:

(Interface to Aspect BISx device cleared in K 040183)

The BIS Module is used to monitor dual channel EEG waveform and the BIS index, used to estimate the level of conciseness of patient under anesthesia, or patients in the ICU that may be with limited conciseness.

The BIS index together with several quality parameters are displayed and stored by the Envoy monitor.

The parameters displayed and stored by the Envoy monitor are the following:

Parameter	Range	Description
BIS	0 – 99	**Bispectral Index:** The measure of consciousness of a patient, (0 = no brain activity), (100 = fully conscious).
EMG	30 – 55 dB	**Electromyography:** The absolute power of muscle activity and artifacts in the 70 - 110 Hz range. Value is in dB with respect to 0.0001 μV_2.
SQI	0 – 100 %	**Signal Quality Index:** The percentage of good epochs and suppressed epochs in the last 120 epochs collected that could be used in the Bispectral Index calculation.
SR	0 – 100 %	**Suppression Ratio:** The percentage of epochs in the past 63 seconds in which the EEG signal is considered suppressed
BC	0 – 30	**Burst Count:** The number of EEG bursts in the last minute. An EEG burst is a momentary period of EEG activity among isoelectric or flat EEG. Blanked if SR is less than 5. Activated by connection of an Extend sensor.
SEF	0.5 – 30 Hz	**Spectral Edge Frequency:** The frequency at which 95% of the total power lies below it and 5% lies above it.

To get these parameters we use Aspect sensor and BISx unit attached to the Envoy BIS module with an interface cable produced by Aspect.

The BISx is a product of Aspect and is sold to Mennen Medical under OEM agreement.

The BIS sensors, that consist of a set of 4 electrodes, attached to the patients forehead, are Aspect products and will be sold to end users by Aspect directly and not by Mennen Medical.

The function of the Envoy BIS module and Envoy display and storage capabilities is to display the BIS parameter and the quality parameters. To provide alarm limits for the BIS index and provide visual and audible alarms in case of the BIS index being out of the preset range, or in cases that the quality parameters are in such range that they limit the reliability of the BIS index.

The decision on artifacts and limited reliability are provided to the Envoy BIS module by the BISx. Those can not be set by Mennen Medical Envoy monitor. The clinical BIS alarm limits are set by the user, on the Envoy monitor.

The Description of the BIS measurement system is described below:

1. The BIS sensor (Made and sold by Aspect) is attached to the patients forehead. (See attached Aspect document: "The BIS™ Family of Sensors")
2. BISx (Figure 1 - OEM by Aspect) is receiving, amplifying and digitizing the EEG brain signals. It analyses the EEG and creates the BIS index and the quality parameters and sends them to the BIS module by RS232 protocol
3. Envoy BIS Module receives the BISx output and transfers it to the Envoy bedside computer for display and storage.
4. BIS Display and storage: BIS is displayed as a number. EMG and SQI are displayed as vertical bars, and SR and BC as numbers in the BIS display area.
5. Clinical and technical alarm messages are displayed in the BIS display area.
6. Continuous graphic trend of the BIS index and quality parameters are also available on the screen under the label CRG.
7. The real time EEG signal is continuously displayed on the monitor screen.
8. In edition, the Envoy provides long term storage and display of the BIS index and its related parameters as numeric Charts and graphic Trends.

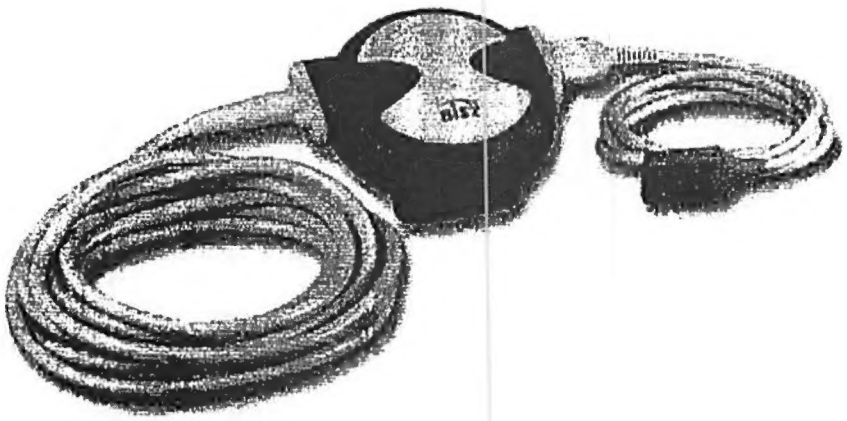


Figure 1: BISx™ device

Substantial Equivalence Discussion

Comparison of the Envoy BIS Module with the predicated device Spacelab Bispectral Index (BISx) analysis module 91482

Comparison of the indication for use

Spacelab Indication for Use

The Spacelabs Medical Bispectral Index (BISx) Analysis Module 91482

is intended for use under the direct supervision of a licensed healthcare practitioner or by personnel trained in its proper use. It is intended for use on adult and pediatric patients within a hospital or medical facility providing patient care to monitor the state of the brain by data acquisition of EEG signals.

The Spacelabs Medical Bispectral Index (BISx) Analysis Module 91482

may be used as an aid in monitoring the effects of certain anesthetic agents. Use of BIS monitoring to help guide anesthetic administration may be associated with the reduction of the incidence of awareness with recall in adults during general anesthesia and sedation.

Mennen Indication for use

The Mennen Medical Envoy BIS module is intended for use under the direct supervision of a licensed healthcare practitioner or by personnel trained in its proper use. It is intended for use on adult and pediatric patients within a hospital or medical facility providing patient care to monitor the state of the brain by data acquisition of EEG signals.

The Mennen Medical BIS module may be used as an aid in monitoring the effects of certain anesthetic agents. Use of BIS monitoring to help guide anesthetic administration may be associated with the reduction of the incidence of awareness with recall in adults during general anesthesia and sedation.

Conclusion

The indication for use of Mennen Medical BIS module and of the predicated device, has the same wording. The only difference between the two is the module and company name.

Specification Comparison

	Spacelab Bispectral Index (BISx) Analysis	**Envoy BIS Module**
Part Number	Module 91482	551-147-000
510K	K060900	
Features		
Display format: Single zone	BIS Numeric and BIS Trend	BIS numeric + one EEG + EMG vertical bar + EMG vertical bar + SR, BC numeric

	Spacelab Bispectral Index (BISx) Analysis	Envoy BIS Module
Single zone Waveform + trend		BIS numeric + Two EEG + EMG vertical bar + EMG vertical bar + SR, BC numeric + Trend of BIS and EMG
Dual zone	N/A	BIS numeric + Two EEG + EMG vertical bar + EMG vertical bar + SR, BC numeric
Three zone	BIS + EMG trends +one EEG	BIS numeric + Two EEG + EMG vertical bar + EMG vertical bar + SR, BC numeric + Trend of BIS and EMG
Four zone	N/A	BIS numeric + Two EEG + EMG vertical bar + EMG vertical bar + SR, BC, numeric + Trend of BIS and EMG + Trend of any two other parameters
Waveform + Trend	N/A	EEG waveform and BIS + EMG graphic trend
Wave scale	+/- 2, 5, 10, 20, 50, 100, 200, 400 μV	5, 10, 25, 50, 100 μV/cm
EEG sweep speed	12.5, 25, 50 mm/sec	6.25, 12.5, 25 mm/sec
BIS Task window	BIS, EEG waveform, EMG, SQI, SR, SEF, MF, Alarm limits	BIS, EEG waveform, EMG, SQI, SR, BC, Alarm limits, Alarm messages
Data Storage	24 hours of: BIS, Spectral Edge Frequency (SEF), Median Power Frequency (MF) Electromyography strength (EMG) Signal Quality Index (SQI) Suppression Ratio (SR)	EEG waveform – 45 days 3 month of: BIS, Spectral Edge Frequency (SEF), Electromyography strength (EMG) Signal Quality Index (SQI)

	Spacelab Bispectral Index (BISx) Analysis	Envoy BIS Module
	Burst Count (BC)	Suppression Ratio (SR) Burst Count (BC)
Electrode Impedance testing	Manual or Auto by BISx	Auto on connection of sensor and Manual any time
Patient compatibility	Adult and pediatric	Same
Input Specification	**Set By BISx**	**Set By BISx**
Number of channels	Two	Same
Sweep speed	15, 30, 50 mm/second	6.25, 12.5, 25 mm/second
EEG Input signal	+/- 1μV to +/-400 μV	Same
EEG Bandwidth	0.25 to 100 Hz	Same
EMG bandwidth	70 to 110 Hz	Same
DC offset	+/- 300 mV	Same
Input Impedance	>50 MΩ	Same
Input Capacitance	<100 pF	Same
Common Mode rejection	> 110dB	Same
Input Noise	<0.3 μV RMS (2.0μV peak to peak to peak)	Same
Smoothing rate	10, 15, or 30 seconds	Same
Electrical Specification		
Patient leakage currant	< 100 μV	
Isolation	4000VAC	
Operating Voltage	+5 VDC , +/- 12 VDC	Same
Power consumption	4.5 Watt maximum	1.5 Watt
Alarms	Audible for High and Low BIS	Audible and visual (red background)
	Caution alarm	Audio and visual (yellow background) and alarm

	Spacelab Bispectral Index (BISx) Analysis	Envoy BIS Module
		message
Classification	**MDD** Class IIb **EN 60601-1** Externally powered, rated for continuous operation	Same
Aspect BISx pod	Type BF, defibrillator proof, Body floating applied part	Same
Environmental Requirement		
Storage	Temperature: -25° to 60° C Humidity : 95% (non-condensing) Altitude: 0 to 12,192 m	Temperature: -15° to 60° C Humidity : 10 to 95% (non-condensing) Altitude: -350 to 5,000m
Operating	Temperature: 0° to 40° C Humidity : 95% (non-condensing) Altitude: 0 to 4,572 m	Temperature: +5° to 40° C Humidity :10 to 95% (non-condensing) Altitude: -350 to 3,050 m

Envoy BIS module and Spacelab BIS analysis module: Similarities and Differences:

Similarities:

The following technological and other characteristic/features apply to both Envoy BIS module and Spacelab 91482 Bispectral Index (BISx) module:

- Both use Aspect Medical Systems BISx pod as their input device
- Both provide the BISx pod its power (5 Volt)
- Both receive from the BISx by serial data communication the EEG waveform and the BIS parameter together with its quality and related parameters.
- Both have the capability to display EEG waveform and BIS numeric parameters
- Both enable correlation between BIS and other vital signs displayed and stored by the monitor to which the BIS module is inserted.

Differences:

The difference between the BIS parameters display of the Envoy monitor and the Spacelab monitors are mainly due to the format of the display of the different monitors.

- The Spacelab BIS module is compatible with a family of Ultraview monitors, while the Mennen Medical BIS module is for the Envoy monitor only.
- There are differences in the display options of the Spacelab Ultraview BIS display that has two display formats: Single Zone and Three-zone while the Envoy monitor has at least 6 options of display for BIS value and parameters. The differences, however, do not change the efficiency of BIS and EEG displays of both monitors.
- Data storage of the Spacelab Ultraview monitor is for shorter duration of the Envoy.

Conclusion of comparison

We consider the Envoy BIS module to be substantially equivalent to the Spacelab 91482 Bispectral Index module.

Any differences between to two monitors for the display of BIS, EEG and related parameters do not raise any new issues of safety and effectiveness.

The Intended use of the Mennen medical Envoy BIS module and the predicated device is the same.

Verification, Validation and Testing

The Envoy BIS module has been subject to extensive performance testing to ensure that:
1. The acquisition and display of the patient data and waveforms by the **Envoy** with BIS - 550-OPT-400 are equivalent to the predicate device Spacelab with BIS module.

At the system level, SW Validation of the performance of the Envoy with 550-OPT-400 as compared to the Spacelab with BIS module, was carried out in accordance with the test plan described in the Mennen Medical Validation Test Procedure for the Envoy BIS module.

The SW Test Description for the Envoy with BIS - 550-OPT-400 was derived from the SW Test Description for the Envoy, with the necessary addition of the BIS measurements

Final testing for the Envoy BIS module included performance tests designed to ensure that the device meets all functional requirements and performance specifications, in accordance with the requirements of the Final Test Procedure for the Envoy BIS module. Electrical Safety testing and EMC testing were performed by an independent testing laboratory (Standard Institute of Israel SII) to ensure that the device complies to applicable industry and safety standards.

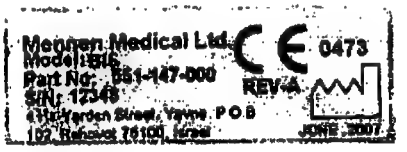
Proposed Labeling

The system will be called **Envoy** with BIS module p/n 550-OPT-400

Page 2-2 of the introduction to the Envoy User Guide contains the following **Prescription Notice:** "Federal United States law restricts the sale and use of this instrument to qualified medical personnel only."

The following symbols appear on page 2-4 of the Envoy User's Guides under the section entitled "Label Symbols".

Symbol	Description	Location of Symbol
	Alternating Current	Rear of the Processing unit, Isolation Transformer, and Module Rack
	Equipotential	On the rear of the Processing unit
	Attention, consult accompanying documents (Service to be performed by qualified technician, consult service manual before removing cover)	On Isolation Transformer and Processing unit.
	Off (power disconnection from main power supply)	On right of Processing unit
	On (power connection to the main power supply)	On the right of the Processing unit.
	Type BF applied part defibrillator-proof	On NIBP and Sp02 modules.
	Type CF applied part - direct cardiac application defibrillator-proof	On ECG, and Dual BP and CO/2 TMP modules
	Fuse	On rear of Processing unit and Isolation Transformer



Voluntary Standards

Appropriate voluntary standards for this device, to which conformance have been demonstrated:

- **IEC 60601-1** (2005)
  General Requirement for Safety for Medical Electrical Systems - part 1,
  Amendment 1 – 1991-11
  Amendment 2 – 1995-03

- **IEC 60601-1-1** (2000)

  Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems

- **IEC 60601-1-2** (2007):
  Medical electrical equipment. General requirements for Safety. Electromagnetic Compatibility Requirements and Tests.

- **IEC 60601-2-27** (2005):
  Medical electrical equipment, Part 2,
  Requirements for safety of electrocardiograph monitoring equipment.

- **IEC 60601-2-30** (1999):
  Medical electrical equipment, Part 2 - requirements for safety of automatic cycling indirect blood pressure monitoring equipment

- **IEC 60601-2-34** (2005):
  Medical electrical equipment, Part 2 - Particular requirements for the safety of direct blood pressure monitoring equipment

- **IEC 60601-2-49** (2006):
  Particular Requirements for the safety of multifunction patient monitoring equipment

Indications for use - BIS Module

The Mennen Medical Envoy BIS module is intended for use under the direct supervision of a licensed healthcare practitioner or by personnel trained in its proper use. It is intended for use on adult and pediatric patients within a hospital or medical facility providing patient care to monitor the state of the brain by data acquisition of EEG signals.
The Mennen Medical BIS module may be used as an aid in monitoring the effects of certain anesthetic agents. Use of BIS monitoring to help guide anesthetic administration may be associated with the reduction of the incidence of awareness with recall in adults during general anesthesia and sedation.

- The Bispectral Index is a complex technology, intended for use only as an adjunct to clinical judgment and training.

- In addition, the clinical utility, risk/benefit, and application of this device have not undergone full evaluation in the pediatric population.

*The Intended Use of the Envoy monitor as indicated above are same as the Indications For Use.

Confidentiality

Mennen Medical Ltd. considers its intent to market the Envoy with 550-OPT-400 BIS module option, to be confidential commercial information. The company has not disclosed its intent to market this device to anyone except its employees, others with a financial interest in the company, its advertising and law firms, and its consultants. Mennen Medical, therefore, requests the FDA not disclose the existence of this application until such time as final action on the submission is taken.
In addition, some of the material in this application may be trade secret or confidential commercial or financial information within the meaning of 21 CFR § 20.61 and therefore not disclosable under the Freedom of Information Act, even after the existence of the application becomes public. We ask that FDA consult with the Company as provided in 21 CFR § 20.45 before making any part of this submission publicly available.

Attachment:

Envoy Patient Monitor, User Manual – part 13 d

FTP for Bis option in Envoy Patient Monitor – Part 16 j 2

Changes to Envoy Patient Monitor – BIS Risk Analysis – part 16 d

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mennen Medical Ltd.
c/o Mr. Ifat Oren
4 Ha-Yarden Street, Yavne
P.O. Box 102
Rehovot 76100
Israel

APR - 9 2012

Re: K071899
Trade/Device Name: BIS Module for Envoy Patient Monitor
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: OLW, OMC, OLT, MHX, ORT
Dated (Date on orig SE ltr): September 17, 2007
Received (Date on orig SE ltr): September 21, 2007

Dear Mr. Oren:

This letter corrects our substantially equivalent letter of October 22, 2007.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Kesia Alexander

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K071899**

Device Name: **BIS Module for Envoy Patient monitor**

Indications For Use:
We submit that the intended use and the indications for use of the Envoy have been affected by the changes only by the addition of the new BIS parameter. Other aspects of the Envoy monitor where not changed.

Envoy Indications for Use:

The ENVOY Monitor is a physiological patient monitor intended to be used for monitoring vital signs of critically ill adult and pediatric patients in the hospital environment, such as: ECG/Heart Rate, Invasive Blood Pressure, Respiration, Temperature, Noninvasive Blood Pressure, CO, Pulse Oximetry, and $EtCO_2$. The ENVOY may be used to monitor a wide range of patient conditions in many different clinical specialties within the hospital. The device is intended for use by qualified health care providers, who will determine when use of the device is indicated, based upon their professional assessment of the patient's medical condition.

Indications for use - BIS Module

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- In addition, the clinical utility, risk/benefit, and application of this device have not undergone full evaluation in the pediatric population.

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Prescription Use __YES__ AND/OR Over-The-Counter Use __NO__
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K071899